

# SPL ER/DL Meeting

## Meeting Minutes

### Mar 13, 2013

Chair of today's meeting: Pat Cowall-Hanover

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

#6: Mute

\*6: Unmute

Agenda:

1. The PLR Guidance was recently updated and is attached. See page 16 and 17 of the guidance.  
(Kathi Lins-Hospira)

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075082.pdf>

Here is the exact verbiage that appears in the Guidance:

#### *15. Revision Date (§ 201.57(a)(15))*

At the end of Highlights, the date of the most recent revision of the labeling must be presented (§ 201.57(a)(15)). The preferred format is **Revised: Month Year** or **Revised: Month/Year** in bold type (i.e., **Revised: Apr 2011** or **Revised: 4/2011**). In PLR format, this statement replaces the revision date that appears at the end of labeling in the old format (§ 201.56(e)(5)). A new approval or changes to the approved labeling will trigger a new revision date. FDA-approved patient labeling or Medication Guides can have revision dates that differ from the revision date at the end of Highlights, if appropriate.

- ☐ For labeling requiring prior approval (e.g., original applications, efficacy supplements, prior approval labeling supplements), the revision date would be the date of application approval. Manufacturers should leave this field blank and FDA will populate it at the time of approval.
- ☐ For CBE supplement labeling (§§ 314.70(c)(6) and 601.12(f)(2)), the revision date generally is the date of application receipt. Manufacturers should populate the revision date field with the date they anticipate FDA will receive the supplement. If the labeling text is changed by FDA, the revision date will be changed to the date of CBE approval.
- ☐ For annual report labeling, the revision date should reflect the date that the revised labeling is submitted to FDA. If all such changes are bundled and submitted once a year

with the annual report, the revision date should be the date of the receipt of the annual report.

We would like to know if the above pertains to the SPL and the Word document?

For the first bullet point it says to leave the field blank. Our software does not allow this field (effective time) to remain blank.

How are other companies managing the above when it comes to SPL?

Discussion:

- The PLR guidance refers to the MSWord and printed labeling.
- Submitted/unapproved labeling – leave blank. What do you do in the SPL?
  - o Several companies enter 00/00/0000 in the SPL.
  - o Some companies software won't let you put in 00/00/0000. In those situations, customers put in a date VERY far in the future, so that there is no change the labeling will be approved in this timeframe.
- SPL automatically puts the effective time of the SPL file in the highlights section. This leads to inconsistencies between the SPL and the MSWord and printed document.
  - o The version number always has to be increased.
  - o In the SPL, there are no requirements about the document approval date.
  - o What date do folks enter into the SPL version number field? Companies deal with this in different ways.
    - Many companies update the revision date whenever any component of the SPL changes. This is because we want readers to be able to differentiate between different versions of SPL. Thus the SPL date will not necessarily be the date on the USPI.
    - Some companies leave the date of approval of the USPI.

2. Differentiated NDC Numbers and the following examples: [\(Kathi Lins-Hospira\)](#)

NDC Number	Package Description
0409-2222-01	5 TRAY In 1 PACKAGE
	5 AMPULE In 1 TRAY
	2 mL In 1 AMPULE

NDC Number	Package Description
0409-3333-01	24 POUCH In 1 CASE
	1 BAG In 1 POUCH
	200 mL in 1 BAG

We are in the process of assigning a differentiated NDC number for our unit of use.

In the first example do we also need another NDC Number for the middle package? Or should we just remove this middle level and only show the unit of use and saleable unit?

In the second example do we need to mention the 1 BAG In 1 POUCH, or can we remove this level and only show the unit of use and saleable unit?

Any advice is greatly appreciated as this is new territory for us.

Discussion:

- CDER products, NDCs are provided on the saleable unit and the unit of use.
  - o For CDER products, the middle level does not have to be removed and it would not have an NDC code on the middle layer
- CBER products, per previous discussion with Vada Perkins, every level/layer of packaging, they would all have a separate NDC (Baxter).
- See validation procedure 3.1.5.12 – if the document type is cellular.... , then there needs to be NDCs on every level of packaging ...except if the inner package is wrapped into a pouch. You can put the NDC code on the pouch level.
  - o Reason is that you want the NDC code on the level that can have a label that is scannable. Inner level is sterile.

3. What happens when a company runs out of NDC numbers? For example, FDA assigned 3 digits for my company's product codes so we have 999 NDC numbers available to us. What happens when we have 1,000 products on the market? (Donna Alvarez)

Discussion: Two options:

- You request a new labeler code.
- If you have bought a company, you can use their company code.

4. We have been assigning NDC numbers to twin packs/combo packs and drug listing them. Is this an FDA requirement or are we being overzealous? (Donna Alvarez)

Discussion:

- OTC specific discussion
- Twin packs of the same product:
  - o If you shrink wrap multiple unit sales together, and are selling them separately, then you don't create a new NDC.
  - o If you put them together, with a separate label, then they are a different package size, and should have a different NDC.
- Combo packs: if you create a new carton or have a new label with double the volume, then you must create a new NDC.

5. Are we required to drug list BOGOs- buy one and get one free? For example, if our distribution center wraps clear cello over two 6 oz bottles and puts a BOGO sticker on it, is it required to be drug listed (the 6 oz bottles would already be listed). (Donna Alvarez)

Discussion:

- OTC drugs only
- BOGOs: Since these are promotionals -- you are getting one free -- then they don't create a new NDC number.

6. Follow-up to converting grams to liters for expressing strength – SPL can't have volume to volume units of measure (Howard Shatz)

Discussion:

- Need to contact the chemist and use information about the specific ingredient to convert the ml to grams.

7. Annual reports – when are they submitted? What if you have different strengths approved at different times.

- Annual reports are submitted at the anniversary date of the NDA
- If you have multiple NDAs, then you can negotiate with FDA to synch up the annual report dates.

8. How do you request a new labeler code?

- Submit the SPL labeler code request with the code blank
- FDA sends you back a label code
- Resubmit the labeler code request with the code completed.

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Long-term topics that we want to keep on our radar screen:

- Registering of excipients under FDASIA:
  - When will we be seeing more info on this?
  - Are OTCs required to register excipient manufacturers under FDASIA?
- Migration of ER/DL data to IDMP – this discussion should go to the SPL tech team, with a follow-up to our SPL Process Team